

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
TYLER DIVISION**

THE STATE OF TEXAS; TEXAS	§	
HEALTH AND HUMAN SERVICES	§	
COMMISSION	§	
	Plaintiffs,	§
		§
v.		§ CIVIL ACTION NO. 1:21-CV-191
		§
CHIQUITA BROOKS-LASURE, in	§	
her official capacity as	§	
Administrator of the Centers	§	
for Medicare & Medicaid Services,	§	
et al.	§	
	Defendants.	§

**DEFENDANTS' COMBINED OPPOSITION TO PLAINTIFFS' MOTION FOR  
PRELIMINARY INJUNCTION AND MOTION TO  
DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION**

## TABLE OF CONTENTS

I.	Introduction .....	1
II.	Factual and Procedural Background .....	2
III.	Standard of Review .....	5
IV.	Argument.....	6
	a.    Texas Has Not Established Entitlement to Preliminary Injunctive Relief .....	7
	i.    Texas Seeks A Mandatory Injunction and Cannot Satisfy The Heightened Standard That Applies. ....	7
	ii.    Texas Will Not Suffer Irreparable Harm If The Preliminary Injunction Is Denied.....	7
	1.    Texas Has No Likelihood of Suffering Any of the Harm Alleged During the Pendency Of The DAB Administrative Appeal Process.....	8
	2.    Even if Texas's DAB appeal were not pending, Texas's Alleged Harms Are Not Irreparable and Would Not Be Prevented by a Preliminary Injunction .....	9
	iii.    Texas Has No Likelihood Of Success On The Merits .....	12
	1.    This Court Lacks Subject Matter Jurisdiction to Consider Plaintiffs' Claims.....	13
	iv.    CMS's January 2021 Approval Of Texas's Extension Request Was In Excess Of The Agency's Authority And Is Therefore Void .....	15
	v.    CMS's April 16 Letter Did Not Constitute Agency Action .....	20
	vi.    If the April 16 Letter Constitutes Agency Action, CMS Acted Within Its Authority .....	21
	vii.    Texas's Additional Merits Arguments Are Unavailing .....	23
	b.    Plaintiffs Have Not Demonstrated That The Balance Of The Equities Or The Public Interest Favors An Injunction .....	27
V.	Plaintiffs' Suit Should Be Dismissed For Lack Of Subject Matter Jurisdiction.....	28
VI.	Conclusion .....	29

## TABLE OF AUTHORITIES

### CASES

<i>Alfred L. Snapp &amp; Son v. Puerto Rico,</i> 458 U.S. 592 (1982) .....	12
<i>Barrera-Montenegro v. United States,</i> 74 F.3d 657 (5th Cir. 1996) .....	6
<i>Bluefield Water Ass'n Inc. v. City of Starkville,</i> 577 F.3d 250 (5th Cir. 2009) .....	6, 11
<i>Brooklyn Legal Servs. Corp. v. Legal Servs. Corp.,</i> 462 F.3d 219 (2nd Cir. 2006) .....	15
<i>Daniels Health Scis., LLC v. Vascular Health Scis., LLC,</i> 710 F.3d 579 (5th Cir. 2013) .....	9
<i>Darby v. Cisernos,</i> 509 U.S. 137 (1993) .....	14
<i>Davis v. Angelina Coll. Bd. of Trustees,</i> Case No. 17-cv-179, 2018 U.S. Dist. LEXIS 61798 (E.D. Tex. Apr. 11, 2018) .....	6, 7, 13
<i>Dennis Melancon, Inc. v. City of New Orleans,</i> 703 F.3d 262 (5th Cir. 2012) .....	9
<i>Elam v. Kansas City Ry.,</i> 635 F.3d 796 (5th Cir. 2011) .....	15
<i>ExxonMobil Pipeline Co. v. U.S. Dep't of Transp.,</i> 867 F.3d 564 (5th Cir. 2017) .....	22
<i>Houston Chronicle Publ'g Co. v. City of League City, Tex.,</i> 488 F.3d 613 (5th Cir. 2007) .....	14
<i>Humana Inc. v. Jacobson,</i> 804 F.2d 1390 (5th Cir. 1986) .....	9
<i>Jefferson Cnty. Health Care Ctrs., Inc. v. Jefferson Parish Gov't,</i> 849 F.3d 615 (5th Cir. 2017) .....	12, 13
<i>Lake Charles Diesel, Inc. v. Gen. Motors Corp.,</i> 328 F.3d 192 (5th Cir. 2003) .....	5
<i>Lujan v. Defenders of Wildlife,</i> 504 U.S. 555 (1992) .....	14

<i>M.D.C.G. v. United States,</i> 956 F.3d 762 (5th Cir. 2020) .....	13
<i>Macktal v. Chao,</i> 286 F.3d 822 (5th Cir. 2002) .....	21, 22, 25
<i>Martinez v. Mathews,</i> 544 F.2d 1233 (5th Cir. 1976) .....	6
<i>Mississippi State Democratic Party v. Barbour,</i> 529 F.3d 538 (5th Cir. 2008) .....	14, 15
<i>Nken v. Holder,</i> 556 U.S. 418 (2009).....	27
<i>Occidental Chem. Corp. v. Louisiana PSC,</i> 810 F.3d 299 (5th Cir. 2016) .....	15
<i>Optimus Steel, LLC v. U.S. Army Corps of Engineers,</i> 492 F. Supp. 3d 701 (E.D. Tex. 2020).....	8
<i>Smith v. Regional Transit Auth.,</i> 756 F.3d 340 (5th Cir. 2014) .....	6
<i>Southern Recycling, L.L.C. v. Aguilar,</i> 982 F.3d 374 (5th Cir. 2020) .....	6
<i>Sierra Club v. United States EPA,</i> 939 F.3d 649 (5th Cir. 2019) .....	22
<i>Texas v. United States,</i> Case No. 21-cv-00003, ____F. Supp. 3d____, 2021 U.S. Dist. LEXIS 33890 (S.D. Tex. Feb. 23, 2021) .....	27
<i>Texas v. Ysleta Del Sur Pueblo,</i> Case No. 17-cv-179-PRM, 2018 U.S. Dist. LEXIS 54042 (W.D. Tex. Mar. 29, 2018).....	7
<i>Warth v. Seldin,</i> 422 U.S. 490 (1975).....	15
<i>Valerio v. Limon,</i> Case No. 20-cv-040, 2021 U.S. Dist. LEXIS 67590 (S.D. Tex. Feb. 4, 2021) .....	13
<i>Winter v. NRDC, Inc.,</i> 555 U.S. 7 (2008) .....	27
<i>Worldcall Interconnect, Inc. v. FCC,</i> 907 F.3d 810 (5th Cir. 2018) .....	22

**STATUTES**

5 U.S.C. § 702.....	13
5 U.S.C. § 704.....	13
42 U.S.C. § 1315 .....	<i>passim</i>

**RULES**

Fed. R. Civ. P. 12 .....	6
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**REGULATIONS**

42 C.F.R. § 430.3 .....	13
42 C.F.R. § 431.412.....	24
42 C.F.R. § 431.416.....	<i>passim</i>
42 C.F.R. § 431.420.....	21
42 C.F.R. § 431.424.....	25
45 C.F.R. Part 16.....	4, 5, 13
45 C.F.R. Subpart G .....	11
45 C.F.R. § 16.22 .....	5, 8
45 C.F.R. § 16.23 .....	9

## I. Introduction

Plaintiffs come before the Court to demand extraordinary relief that they do not need and that would require Defendants to take actions in excess of their authority. Notwithstanding the relief requested in Plaintiffs' motion, and indeed in this entire lawsuit, the Texas Healthcare Transformation Quality Improvement Program ("THTQIP" or the "demonstration project") will continue to allow Texas's Medicaid program to operate unchanged through September 30, 2022. Nevertheless, Plaintiffs seek to immediately enforce a nearly ten-year extension of THTQIP that was improperly approved by Defendants in a January 15, 2021 letter (hereinafter "January 15 Letter" or "January approval") without the notice and comment process required by statute and regulation. Through a letter dated April 16, 2021 (hereinafter "April 16 Letter"), Defendants notified Plaintiffs that the January approval was made in excess of Defendants' statutory and regulatory authority and was therefore void and without legal effect.

Preliminary injunctive relief is clearly unwarranted. Plaintiffs lack any likelihood of eventual success on the merits, because the alleged underlying agency action they seek to enforce, the January 15 Letter, is in excess of the agency's authority and thus void. Plaintiffs also cannot show a likelihood that they will suffer harm if extraordinary relief is not granted during the pendency of the case. Plaintiffs' concurrent administrative appeal of the April 16 Letter before the Department of Health and Human Services ("HHS") Departmental Appeals Board ("DAB") obliges Defendants to treat the January 15 Letter as in effect until the conclusion of that appeal. This regulatory requirement currently provides Plaintiffs with the identical relief they seek from this Court as a preliminary injunction. Moreover, because the prior approval of the THTQIP project does not expire for more than a year (until September 30, 2022), Plaintiffs have ample opportunity to reapply for an extension after complying with the necessary notice

and comment process. And indeed, at the time of filing this opposition, Plaintiffs have submitted a new application for extension of THTQIP that is under separate consideration by Defendants.

This case should also be dismissed for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). The Court lacks jurisdiction to consider Plaintiffs' claims under the Administrative Procedure Act ("APA") because there has been no final agency action and because Plaintiffs' claims are not ripe and Plaintiffs lack standing.

For the reasons explained below, Plaintiffs' Motion for Preliminary Injunction should be denied, and their case as a whole should also be dismissed for lack of subject-matter jurisdiction.

## II. Factual and Procedural Background

Forty-two U.S.C. § 1315(a) permits the Secretary of HHS to "waive compliance with any of the requirements" of various sections of the Social Security Act ("SSA") to allow states to engage in "any experimental, pilot, or demonstration project, which, in the judgment of the Secretary, is likely to assist in promoting the objectives," of Medicaid. Defendant, the Centers for Medicare & Medicaid Services ("CMS"), first approved Texas's current demonstration project, THTQIP, in December of 2011. Defs.' Ex. 1, January 15 Letter, at 3.<sup>1</sup> The demonstration project authorizes certain Medicaid expenditures throughout the state of Texas through a variety of programs, and also includes two funding pools, the Uncompensated Care Pool and the Delivery System Reform Incentive Payment ("DSRIP"). *See id.* THTQIP was renewed first in 2016 and then again in 2017. *See* Compl. ECF No. 1, ¶ 5. The 2017 extension of THTQIP slated the project as a whole to expire on September 30, 2022. *See* Defs.' Ex. 2, April 16 Letter, at 1-2. The 2017 extension also imposed a separate September 30, 2021 expiration date for the DSRIP.

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<sup>1</sup> Unless otherwise noted, for the Court's convenience Defendants' exhibits are presented without voluminous, secondary attachments duplicative of Plaintiffs' submissions or not relevant to the motions under consideration.

*See* Defs.’ Ex. 3, Declaration of Judith Cash (July 26, 2021), ¶ 13. Under the terms of the 2017 extension, the DSRIP would not be renewed and Texas was obliged to wind down the program and transition out of federal funding for DSRIP by the scheduled September 30, 2021 end date.

*Id.*

On November 27, 2020, approximately 22 months before the scheduled expiration of THTQIP as a whole, Plaintiffs sent CMS the application for extension of the demonstration project that is the subject of this litigation. Compl. ¶ 63. This extension application, identified as a “Section 1115 Demonstration Extension Section 1115(a) Fast Track Application,” *see* Cash Decl. at 30 (Ex. E), requested an extension of 5 years, *id.* at 25, and an exemption from participation in the federal public notice and comment period mandated by the statute and regulations, *id.* at 70-71. Texas asserted that it was seeking to waive the federal notice and comment requirements of 42 C.F.R. § 431.416 because “[t]he state’s health care system [was] experiencing significant pressure and uncertainty as Texas continues to respond to the Public Health Emergency,” created by COVID-19. *Id.* at 70. The application also informed CMS that Texas was on track to wind down its DSRIP program and did not request an extension. Cash Decl. ¶ 13. On December 15, 2020, CMS informed Texas that its application for extension was complete and that it was “exempt from the requirements for public notice and comment.” Cash Decl. at 23 (Ex. E).

On January 15, 2021, CMS approved a nearly ten-year extension of THTQIP, through September 30, 2030, with several significant changes from the original demonstration. *See generally*, Ex. 1, January 15 Letter. The January approval does not extend DSRIP and neither the Texas nor CMS expected that it would. *See id.* at 3. One change purportedly approved by the

January 15 Letter was the creation of a new uncompensated care pool, the Public Health Providers Charity Care Pool (“PHP-CCP”), to commence on October 1, 2021. *Id.* at 3-4.

On April 16, 2020, CMS issued a subsequent letter informing Texas that “CMS materially erred in granting Texas’s request for an exemption from the normal public notice process under 42 C.F.R. § 431.416(g),” because the state’s request “did not articulate a sufficient basis for [CMS] to conclude that approving the state’s emergency request...was needed to address a public health emergency or other sudden emergency threat to human lives.” Ex. 2, April 16 Letter at 1-2. The letter explained in detail why “rescission” of the January 15 Letter was necessary based on the facts presented by Texas in its application and the requirements of the applicable statute and regulations. *See generally id.* The April 16 Letter also noted that the existing demonstration project was nevertheless authorized through September 30, 2022 and indicated that “should the state still wish to extend the demonstration past that date, [CMS] stand[s] ready to work with the state to accomplish state submission and CMS review of a complete extension application during the next eighteen months that the demonstration continues to be authorized.” *Id.* at 2.

On May 14, 2021, the same day as the filing of this suit, Plaintiffs filed a Notice of Appeal with the DAB challenging CMS’s April 16 Letter on the basis of its purported rescission of CMS’s January 15 approval. Ex. 4, May 14, 2021 DAB Notice of Appeal. Plaintiffs’ administrative appeal is premised on the same legal and factual grounds as this suit. *See id.* at 3-5. Plaintiffs asserted in their Notice that the appeal was “protective” only because, in their view “the dispute over CMS’s actions does not fall within [the DAB’s] jurisdiction.” *Id.* at 1. Plaintiffs’ argument is premised exclusively on their interpretation of the types of disputes listed as within the DAB’s competence under 45 C.F.R. Part 16, App’x A. *Id.* Pursuant to its

procedures under that same Appendix, the DAB requested that CMS render its opinion on the DAB's jurisdiction to consider the appeal. Ex. 5 Acknowledgement of Appeal and Request to CMS; 45 C.F.R. Part 16, App'x A ¶ G. CMS advised the DAB that it did in fact have jurisdiction to consider the administrative appeal of the April 16 Letter pursuant to 45 C.F.R. Part 16 ¶ C(a)(4). Ex. 6 CMS Response to DAB Request at 2-3. Although the DAB has not yet decided its jurisdiction, per regulation, when, as here, the DAB requests CMS's written opinion regarding jurisdiction, "the [DAB] will be bound by the opinion," "[u]nless the Chair [of the DAB] determines that the opinion is clearly erroneous." 45 C.F.R. Part 16, App'x A ¶ G. Thus, there is little doubt that the DAB will continue to exercise its jurisdiction over the appeal.

Furthermore, during the pendency of a DAB appeal, the agency is barred from taking any action to implement the challenged decision. 45 C.F.R. 16.22(a). CMS has interpreted this requirement to oblige it to implement the January 15 extension approval as though it is not void until the administrative appeal is complete.<sup>2</sup>

Additionally, after the filing of both the instant lawsuit and their administrative appeal, Plaintiffs resubmitted a new application for extension of THTQIP. Ex. 7 July 14, 2021 Extension Application Letter. Plaintiffs' July 2021 extension application does not request an exemption from the required notice and comment procedures.

### **III. Standard of Review**

In order to obtain a preliminary injunction, the party seeking the injunction must establish (1) a substantial likelihood that he will prevail on the merits, (2) a substantial threat that he will suffer irreparable injury if the injunction is not granted, (3) his threatened injury outweighs the threatened harm to the party whom he seeks

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<sup>2</sup> This requirement does not prevent CMS from recovering any funds expended on the basis of an unauthorized approval if CMS eventually prevails on the merits of the DAB appeal and/or this litigation.

to enjoin, and (4) granting the preliminary injunction will not disserve the public interest.

*Bluefield Water Ass'n Inc. v. City of Starkville*, 577 F.3d 250, 252-53 (5th Cir. 2009) (quoting *Lake Charles Diesel, Inc. v. Gen. Motors Corp.*, 328 F.3d 192, 195-96 (5th Cir. 2003)). The Fifth Circuit has “cautioned repeatedly that a preliminary injunction is an extraordinary remedy which should not be granted unless the party seeking it has clearly carried the burden of persuasion on all four requirements.” *Id.* at 253. “A mandatory preliminary injunction—that is, a preliminary injunction that orders a party to ‘take action’ or perform certain acts—is particularly disfavored and should not be issued unless the facts and laws clearly favor the moving party.” *Davis v. Angelina Coll. Bd. Of Trustees*, Case No. 17-cv-179, 2018 U.S. Dist. LEXIS 61798, at \*2 (E.D. Tex. Apr. 11, 2018) (citing *Martinez v. Mathews*, 544 F.2d 1233, 1243 (5th Cir. 1976)).

Defendants also move to dismiss this case for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). “A case is properly dismissed for lack of subject matter jurisdiction when the court lacks the statutory or constitutional power to adjudicate the case.” *Smith v. Regional Transit Auth.*, 756 F.3d 340, 347 (5th Cir. 2014) (internal citation omitted). “The burden of proving subject matter jurisdiction lies with the party asserting jurisdiction, and it must be proved by a preponderance of the evidence.” *Southern Recycling, L.L.C. v. Aguilar*, 982 F.3d 374, 379 (5th Cir. 2020). A 12(b)(1) dismissal may be “based on ‘(1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court’s resolution of disputed facts.’” *Id.* (quoting *Barrera-Montenegro v. United States*, 74 F.3d 657, 659 (5th Cir. 1996)).

#### **IV. Argument**

##### **a. Texas Has Not Established Entitlement to Preliminary Injunctive Relief**

The Court must deny a motion for preliminary injunction if the plaintiff fails to satisfy even one of the prongs of the standard. Texas fails to carry its burden on any of the four prongs, and thus, its motion must be denied.

**i. Texas Seeks A Mandatory Injunction and Cannot Satisfy The Heightened Standard That Applies.**

Texas's brief implies that it is seeking a prohibitory injunction and thus needs to satisfy only the typical preliminary injunction standard. Pl.'s Mot. at 16. But Texas is not seeking merely to enjoin CMS from taking certain actions. It asks the Court to compel CMS to take action under the January 15 Letter, extending the demonstration project with significant modifications, including by providing federal funding for the modified project, during the pendency of the case. Such relief is mandatory in nature. *See, e.g., Davis*, 2018 U.S. Dist. LEXIS 61798, at \*2 (“Plaintiff is seeking a mandatory preliminary injunction that orders the Defendant to overturn his expulsion and allow Plaintiff to attend” Defendant’s college.). Thus, Plaintiffs must satisfy a heightened standard, demonstrating that “the facts and law are clearly in [their] favor.” *Id.* at \*4; *Texas v. Ysleta Del Sur Pueblo*, Case No. 17-cv-179-PRM, 2018 U.S. Dist. LEXIS 54042, at \*24-25 (W.D. Tex. March 29, 2018) (“[T]he Fifth Circuit has repeatedly held that mandatory injunctions warrant an even higher standard than prohibitory injunctions.”) (collecting cases). For the reasons explained below, Texas has failed to meet the typical preliminary injunction standard for each of the four elements of the analysis and has come nowhere close to making the elevated showing necessary to obtain a highly disfavored mandatory injunction.

**ii. Texas Will Not Suffer Irreparable Harm If The Preliminary Injunction Is Denied.**

Texas's clearest failure to satisfy the preliminary injunction standard lies in its inability to demonstrate that extraordinary relief is needed to prevent irreparable harm. Plaintiffs have not

shown, and cannot show, that they will face irreparable harm, or any harm at all, if the requested preliminary injunction is not granted.

**1. Texas Has No Likelihood of Suffering Any of the Harm Alleged During the Pendency Of The DAB Administrative Appeal Process**

Plaintiffs appealed CMS's April 16 letter to the HHS DAB on the same bases as the underlying merits of this suit. The DAB is currently considering, and is expected to continue to assert jurisdiction over, the appeal, activating the Board's procedural regulations. Specifically, pursuant to 45 C.F.R. § 16.22(a), “[u]ntil the Board disposes of an appeal the respondent shall take no action to implement the final decision appealed.”<sup>3</sup> In other words, because Texas timely filed an administrative appeal as to the April 16 Letter, CMS remains bound by its January 15 Approval Letter until the conclusion of the administrative appeal. CMS will treat the January extension of THTQIP as in effect throughout the DAB process. The operation of this regulation provides identical relief to that which Plaintiffs seek through their application for a preliminary injunction—that is, CMS treating the January approval as effective. Therefore, not only have Plaintiffs failed to establish irreparable harm, they cannot establish any harm while their DAB appeal is pending.

Because Plaintiffs are not imminently at risk of suffering any of the harm on which they premise their request for extraordinary relief, their motion for preliminary injunction must be denied. *See, e.g., Optimus Steel, LLC v. U.S. Army Corps of Engineers*, 492 F. Supp. 3d 701, 724 (to meet the irreparable harm requirement “there must be ‘a significant threat of injury from the impending action,’ the injury must be ‘imminent,’ and ‘money damages [can]not fully repair the harm.’” (quoting *Humana Inc. v. Jacobson*, 804 F.2d 1390, 1394 (5th Cir. 1986)).

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<sup>3</sup> The exceptions enumerated in § 16.22(b) are not applicable to the circumstances of this appeal.

**2. Even if Texas's DAB appeal were not pending, Texas's Alleged Harms Are Not Irreparable and Would Not Be Prevented by a Preliminary Injunction**

Irreparable harm is “harm for which there is no adequate remedy at law,” and “speculative injury is not sufficient; there must be more than an unfounded fear on the part of the applicant.” *Daniels Health Scis., LLC v. Vascular Health Scis., LLC*, 710 F.3d 579, 585 (5th Cir. 2013). It is thus well-established that an injury is irreparable only “if it cannot be undone through monetary remedies . . . . Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of [an injunction], are not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, [weighs] heavily against a claim of irreparable harm.” *Dennis Melancon, Inc. v. City of New Orleans*, 703 F.3d 262, 279 (5th Cir. 2012) (internal citations omitted).

Even after the disposition of the DAB appeal, if CMS prevails, Plaintiffs will be unable to demonstrate irreparable harm because their alleged harms are speculative and not irreparable. First, to the extent Plaintiffs’ claim of harm is premised on the possibility that THTQIP as a whole will not be extended before it expires on September 30, 2022, this alleged harm is speculative and not sufficiently impending to warrant entry of a preliminary injunction. There is ample time prior to the September 30, 2022 expiration of the demonstration project to avert Texas’s alleged harm, and there are several pathways for doing so. Plaintiffs’ administrative appeal, or the merits of this lawsuit, or both, could reasonably be expected to be resolved before September 30, 2022. See 45 C.F.R. § 16.23 (establishing goals for duration of DAB appeals). Alternatively, CMS could consider and approve a new extension application before the September 30, 2022 expiration date. In its April 16 letter, CMS invited Texas to resubmit a proper application for extension, including compliance with the required notice and comment period, and indicated a willingness to collaborate with the state as it reviews and considers that application. See April 16 Letter at 1-2.

And, as noted *supra*, Plaintiffs have in fact reapplied to CMS for an extension of the overall THTQIP project, acknowledging the availability of this alternative and likely more expedient resolution. Ex. 7, July 14, 2021 Extension Application Letter.

Second, to the extent that Plaintiffs' alleged harms are premised on the expiration of DSRIP on September 30, 2021, the requested preliminary injunction would provide no relief and is therefore unwarranted. The alleged loss of funding and services Plaintiffs expect to occur, including their "fiscal cliff," is based on the overall termination of DSRIP. *See Pls.' Mot. for Prelim. Inj.* (hereinafter "PI Mot."), ECF No. 11, at 32-33. But the January 15 approval did not extend DSRIP and, consequently, granting the requested injunction would not compel Defendants to extend DSRIP. *See January 15 Letter; Cash Decl. ¶ 13.* Nor have Plaintiffs submitted an application to extend DSRIP. Cash Decl. ¶ 13. Plaintiffs' unsupported claim that they "abandoned" their opportunity to seek an extension of DSRIP when they negotiated the January approval with CMS is unavailing. Plaintiffs have been aware since 2017 that DSRIP would expire on September 30, 2021 and, far from submitting an application to extend DSRIP, Plaintiffs in fact submitted a plan for winding down DSRIP, which CMS approved in 2020. *Id.* Plaintiffs thus had no reasonable expectation that DSRIP would be extended and no legally cognizable harm related to that component of the demonstration. *See id.* Finally, although PHP-CCP would be funded under the January 15 Letter beginning on October 1, 2021 that new demonstration feature is not intended to replace DSRIP, and even if it were it would account for only a small portion, 20% or less, of the prior DSRIP funding. *See id. ¶ 14.* Plaintiffs do not identify what, if any, portion of the "funding cliff" they allege would purportedly result from PHP-CCP not going into effect under the January 15 Letter as opposed to the end of DSRIP or of THTQIP as a whole, which are not implicated by the requested preliminary relief. *See Bluefield Water Ass'n, 577 F.3d at 253* (the

moving party “must clearly carry the burden of persuasion” as to irreparable harm.) Moreover, whether this relatively small amount of lost funding, to the extent it is in fact threatened, would alone lead to any of the purportedly irreparable harms alleged by Plaintiffs, such as the closing of certain medical facilities, is entirely speculative.

Third, Texas’s allegation that it has wasted time and money negotiating and implementing the extension approved in the January 15 letter, PI Mot. at 32, does not entitle it to a preliminary injunction. Any such resources have already been expended, and thus, the prospective injunctive relief Texas seeks will not remedy Plaintiffs’ alleged loss. Moreover, if Plaintiffs eventually prevail on the merits and the January approval is confirmed, those expenditures will no longer be “lost and unrecoverable” because they will be in furtherance of the extended demonstration project.

Fourth, “uncertainty,” *see* PI Mot. at 10-13, 33, is neither a cognizable harm nor would a preliminary injunction provide meaningful relief if it were. No State has an entitlement to the initiation or continuation of a demonstration project in the first instance, and CMS may permit any such project to expire in its sole discretion. *See generally*, 42 U.S.C. § 1315; 42 C.F.R. Subpart G. Additionally, it is apparent from the structure of the applicable statutes that in the absence of demonstration project waivers, states are subject to the default requirements of their Medicaid State Plan. *Cf.* 42 U.S.C. § 1315(a). Therefore, all relevant actors know or should know that they have no guarantee of operating under the auspices of a demonstration project beyond its expiration date, and of the specifics of the program that they will operate under once a demonstration project expires without extension.

Additionally, a preliminary injunction would not meaningfully alleviate the alleged harms of uncertainty in this case, because even if the Court granted a preliminary injunction,

Defendants could still prevail at final judgment. Thus, the uncertainty of whether the State could ultimately operate under the January approval would merely continue through the end of the case. Moreover, because the substance of Defendants' position is that the January approval was void ab initio, a favorable decision for Defendants would invalidate the extension and require the return of any federal money expended on programs authorized solely by CMS's January 15 extension approval. Thus, a preliminary injunction could actually increase uncertainty and result in greater future harm and disruption.

Finally, Texas has no standing parens patriae to represent its citizens against the Federal Government. *Alfred L. Snapp & Son v. Puerto Rico*, 458 U.S. 592, 609 n.16 (1982). And even if it did, for the reasons explained above, there is no threat of irreparable harm to the individual participants in Texas's Medicaid program that would be averted by the injunction Plaintiffs seek. There is no impending threat that THTQIP as a whole will terminate, DSRIIP will expire regardless of the effect of the January 15 Letter; and any other uncertain threat alleged is inherently speculative.

### **iii. Texas Has No Likelihood Of Success On The Merits**

Texas's briefing ignores entirely one necessary element of its obligation to demonstrate a likelihood of success on the merits, subject matter jurisdiction, and gives short shrift to another, the invalidity of CMS's purported January approval. Under normal circumstances, "the party seeking a preliminary injunction must establish at least some likelihood of success on the merits before the court may proceed to assess the remaining requirements." *Jefferson Cnty. Health Care Ctrs., Inc. v. Jefferson Parish Gov't*, 849 F.3d 615, 625 (5th Cir. 2017). However, in the case of a mandatory injunction, Plaintiff must show that the facts and law clearly favor its position. *Davis*, 2018 U.S. Dist. LEXIS 61798, at \*2. Here, Plaintiffs have demonstrated no likelihood of success on the merits whatsoever, and therefore their motion should be denied.

### **1. This Court Lacks Subject Matter Jurisdiction to Consider Plaintiffs’ Claims**

“The United States has sovereign immunity from any lawsuit, unless that sovereign immunity has been waived.” *M.D.C.G. v. United States*, 956 F.3d 762, 767-68 (5th Cir. 2020). Plaintiffs rely exclusively in this case upon the waiver of sovereign immunity contained in the Administrative Procedure Act (“APA”), 5 U.S.C. § 702. Compl., ¶ 25. However, this waiver, and review under the APA, are subject to limitations. The APA “only provides review over ‘[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court.’” *Valerio v. Limon*, Case No. 20-cv-040, 2021 U.S. Dist. LEXIS 67590, at \*8 (S.D. Tex. Feb. 4, 2021) (quoting 5 U.S.C. § 704). “Thus, plaintiffs may not sue under the APA unless....the action they seek to challenge is a final action.” *Id.*

The purported action that Plaintiffs seek to challenge, CMS’s April 16, 2021 letter, is not final agency action. Despite filing this case, Plaintiffs are concurrently engaged in the administrative appeal process specifically provided for such claims by HHS’s regulations. *See supra* at 4-5. Those regulations permit a state wishing to dispute an agency decision related to a discretionary grant, such as a demonstration project, to seek review by the DAB. *See* 42 C.F.R. § 430.3(c), “Appeals under Medicaid” (“Disputes pertaining to discretionary grants, such as grants for special demonstration projects under sections 1110 and 1115 of the Act, which may be awarded to a Medicaid agency, are also heard by the Board.”); *see also* 45 C.F.R. Part 16, “Procedures of the Departmental Grant Appeals Board.” Texas elected to engage in the DAB process by filing a timely and otherwise complete notice of administrative appeal. See Ex. 5, Acknowledgment of Appeal and Request to CMS. “When an aggrieved party has exhausted all administrative remedies expressly prescribed by statute or agency rule, the agency action is ‘final for the purposes of [5 U.S.C. § 704]’ and therefore ‘subject to judicial review.’” *Darby v.*

*Cisernos*, 509 U.S. 137, 146 (1993). In this case, however, Plaintiffs are currently engaged in an ongoing, unexhausted, administrative process that is expressly permitted by regulation, and therefore the challenged action is not final for APA purposes and the Court lacks jurisdiction to consider the case.

For the same reasons, Plaintiffs also do not have standing to bring this suit and their claims are not ripe. The plaintiff bears the burden of establishing both standing and ripeness. *Mississippi State Democratic Party v. Barbour*, 529 F.3d 538, 544 (5th Cir. 2008). To demonstrate standing:

a plaintiff must show: (1) it has suffered, or imminently will suffer, a concrete and particularized injury-in-fact; (2) the injury is fairly traceable to the defendant's conduct; and (3) a favorable judgment is likely to redress the injury.

*Id.* (quoting *Houston Chronicle Publ'g Co. v. City of League City, Tex.*, 488 F.3d 613, 617 (5th Cir. 2007)). “An injury in fact is an invasion of a legally protected interest which is ‘actual or imminent, not conjectural or hypothetical.’” *Id.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). For the reasons explained *supra*, Plaintiffs have no present or imminent injury because, during the pendency of the DAB appeal, Plaintiffs are receiving in substance the exact relief that they request in both their preliminary injunction motion and their Complaint. Plaintiffs’ alleged injury is not imminent because the appeal process is ongoing, and their possible future harm is purely hypothetical because the administrative appeal may be decided in Plaintiffs’ favor, preventing any of the alleged harms from ever coming to pass. The case is similarly not ripe because the alleged harm has not “matured sufficiently to warrant judicial intervention.” *Id.* at 544-45 (quoting *Warth v. Seldin*, 422 U.S. 490, 499 n.10 (1975)). “Ripeness often overlaps with standing, ‘most notably in the shared requirement that the injury be imminent rather than conjectural or hypothetical.’” *Id.* at 545 (quoting *Brooklyn Legal Servs.*

*Corp. v. Legal Servs. Corp.*, 462 F.3d 219, 225 (2nd Cir. 2006)). Because Plaintiffs presently have no actual or imminent injury that is neither conjectural nor hypothetical, they cannot carry their burden to demonstrate either standing or ripeness.<sup>4</sup>

Therefore, the Court lacks subject matter jurisdiction to hear Plaintiffs' APA claims related to CMS's January and April letters at this time. At the conclusion of the administrative appeal process in which Plaintiffs are currently engaged, the Court will have authority to consider the final decision of the DAB. Alternatively, in light of the pending DAB appeal, the Court should stay its consideration of this case; it would be contrary to the interests of judicial economy to simultaneously duplicate the DAB procedures in this Court.

**iv. CMS's January 2021 Approval Of Texas's Extension Request Was In Excess Of The Agency's Authority And Is Therefore Void**

Plaintiffs also cannot show a likelihood of success on the merits because the January 2021 approval they seek to vindicate through this lawsuit was made in excess of the agency's authority and is therefore void. As Plaintiffs note in their motion, federal agencies, including CMS, have only the authority with which they are endowed by statute, PI Mot. at 16, and that authority is further cabined by the requirements of applicable regulations. CMS did not have authority to exempt Texas from the requirements of public notice and comment on the basis of

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<sup>4</sup> If the Court determines that it does have subject matter jurisdiction, it may stay its consideration pending the resolution of the DAB appeal under the doctrine of primary jurisdiction. “[P]rimary jurisdiction attempts to maintain proper relationships between the courts and administrative agencies by suspending judicial process pending the ‘referral’ of certain issues to an administrative agency for its views...” *Elam v. Kansas City Ry.*, 635 F.3d 796, 809 (5<sup>th</sup> Cir. 2011) (citations omitted). Such referral is warranted when the case concerns “questions of fact or law within the peculiar competence of the agency.” *Occidental Chem. Corp. v. Louisiana PSC*, 810 F.3d 299, 309 (5th Cir. 2016). Here the DAB is assessing CMS's interpretation of its own regulations and, inter alia, its assessment of what circumstances might undermine or compromise the purpose the projects it administers or the interests of the beneficiaries it serves. See 42 C.F.R. § 431.416(g). Thus, referral to the ongoing DAB process would serve the interests of good judicial administration.

the justification Texas presented. Thus, CMS's January 15 approval exceeded the agency's authority and is without effect.

CMS's statutory authority to approve demonstration projects is dependent on the promulgation of regulations, providing, *inter alia*, "a process for providing public notice and comment after the application is received by the Secretary, that is sufficient to ensure a meaningful level of public input." 42 U.S.C. § 1315(d)(2)(C). The agency's implementing regulations, promulgated at 42 C.F.R. Subpart G, in turn require CMS to "solicit public comment regarding such demonstration application[s] for 30 days." 42 C.F.R. § 431.416(b). Furthermore, "CMS *will not* render a final decision on a demonstration application until at least 45 days after notice of receipt of a completed application, to receive and consider public comments." 42 C.F.R. § 431.416(e)(1) (emphasis added). The agency may only forego this requirement if the conditions for "exemption from the normal public notice process" are met under § 431.416(g). *See* 42 C.F.R. § 431.416(e)(2). Consequently, if CMS exempted Texas from the notice and comment process, and subsequently approved its extension application, based on a showing that did not satisfy the conditions of § 431.416(g), such actions were ultra vires and without effect.

The record clearly demonstrates that Texas's asserted basis for exemption from the public notice and comment obligation fails to satisfy the requirements of § 431.416(g), and therefore that CMS "materially erred in granting Texas's [exemption] request." April 16 letter at 1. CMS is empowered to waive the public notice and comment requirement on a "demonstration extension request that addresses a natural disaster, public health emergency, or other sudden emergency threats to human lives." 42 C.F.R. § 431.416(g)(1). The requesting state

must establish (or meet) all of the following criteria to obtain such an exemption from the normal public notice process requirements:

- (i) The State acted in good faith, and in a diligent, timely, and prudent manner;

- (ii) The circumstances constitute an emergency and could not have been reasonably foreseen;
- (iii) Delay would undermine or compromise the purpose of the demonstration and be contrary to the interests of beneficiaries.

42 C.F.R. § 431.416(g)(3). Contrary to these strict requirements, Texas's request for an exemption from public notice and comment was "premised on the state's conclusory assertion that healthcare providers in the state must have the financial stability they need to prepare for and respond to the COVID-19 public health emergency, and without an emergency approval of the extension request, the goals, purpose, and achievements from the THTQIP demonstration would be undermined." April 16 Letter at 3.

First, it is plain on the face of the request that the demonstration extension does not "address" the COVID-19 public health emergency as required by § 431.416(g)(1). The requested extension "contained no features that specifically address the COVID-19 public health emergency," and "did not request any new or modified authorities designed to address the COVID-19 public health emergency, or any other sudden emergency threats to human lives." April 16 Letter at 3. Additionally, CMS made available, prior to Texas's request at issue here, "a streamlined section 1115 demonstration application template" specifically to "request and receive expedited CMS approval for new demonstrations and demonstration changes needed to address the exigencies of [COVID-19]." *Id.* at 4. Texas, among other states, was aware of and had already used this separate procedure prior to the extension request at issue in this litigation to make adjustments specifically related to the public health emergency. *Id.* But Texas's demonstration project extension request that is the subject of this case was not submitted pursuant to this special process. Texas's public notice exemption request also did not make a meaningful attempt to explain how its demonstration project extension supposedly addressed COVID-19. *See generally* Cash Decl. at 34-36, 70-71 (Ex. E).

Second, the public notice exemption request does not establish that “the circumstances constitute an emergency.” § 431.416(g)(3)(ii). At the time Texas requested to extend its demonstration project, the project as a whole was slated to continue for nearly two additional years. Although the COVID-19 public health emergency was ongoing, Texas’s application gave no explanation as to why a delay of as little as 45 days to permit notice and comment would “undermine or compromise the purpose of the demonstration [or] be contrary to the interests of beneficiaries.” 45 C.F.R. § 431.416(g)(3)(iii); *see April 16 Letter at 3-4*; 45 C.F.R. § 431.416(e)(1). Assuming for purposes of this analysis only that the expiration of the overall demonstration project on September 30, 2022, would compromise its purpose and be contrary to the interests of the beneficiaries, there was at the time of the extension request, and still remains, ample time for the parties to engage in a compliant extension process. Indeed, Texas acknowledged as much by reapplying for extension of its demonstration project on July 14, 2021. *See July 14, 2021 Extension Reapplication.* Moreover, at the time of Texas’s public notice exemption request, the country was nearly nine months into the pandemic and there was no basis to assert that the conditions of the COVID-19 public health emergency “could not have reasonably been foreseen.” § 431.416(g)(3)(ii).

To the extent Plaintiffs argue that the conditions of the public notice exemption regulations were met with regard to the DSRIP because it was slated to expire on September 30, 2021, Plaintiffs’ explanation still falls far short for the same reasons. Texas had been aware of the expiration of DSRIP since at least December 21, 2017, and knew that federal financial support for that program would wind down by September 30, 2021. At the time Texas sought a public notice exemption, more than ten months remained before DSRIP was set to expire, which provided sufficient time to comply with the necessary notice and comment processes. *See April*

16 Letter at 4. Moreover, Texas did not even request an extension of DSRIP, and thus, there was no justification for expediting the approval in order to forestall the harms that would allegedly flow from the DSRIP expiration. *Id.*, *see also* Cash Decl. ¶13.

Plaintiffs argue that CMS’s analysis is arbitrary and capricious because Plaintiffs’ requested extension “addresses” the COVID-19 public health emergency. PI Mot. at 29-30. Plaintiffs’ assertion that this requirement is met because general features of the existing demonstration project provide services that may be used in connection with a COVID-19 response is a facially implausible reading of 42 C.F.R. § 431.416, and CMS’s contrary conclusion is well within its authority to interpret its own regulations. *See* 42 C.F.R. § 431.416(g)(1); *see also* April 16 Letter at 4 (THTQIP “is not, and has not since its 2011 inception, been designed to address the COVID-19 public health emergency or any other sudden emergency threat to human lives.”). Plaintiffs’ claim that the April 16 Letter asserts that COVID-19 is “irrelevant” to Texas’s extension application is also unfounded. The April 16 Letter notes only that the existence in general of the public health emergency does not bear on Plaintiffs’ improperly supported request to forgo public notice and comment. *See* April 16 Letter at 3-4. Plaintiffs also contend that the April 16 Letter is arbitrary and capricious because it ignores evidence that a public notice exception was necessitated by unforeseen circumstances related to the public health emergency. However, what Plaintiffs actually argue is that they provided evidence to CMS that an extension of THTQIP or DSRIP was necessitated by unforeseen circumstances. *See* PI Mot. at 30-31. The April 16 Letter does not conclude that extension of the demonstration project is improper or unwarranted; it merely concludes that the public notice exemption was not justified and invites Plaintiffs to apply for the extension again while also

complying with the notice and comment requirements (or adequately justifying an exemption).

*See April 16 Letter at 2.*

Weighed against Plaintiffs’ half-hearted attempt to justify an exemption to notice and comment, is the statutory and regulatory mandate to provide transparency and permit public input. *See 42 U.S.C. § 1315(d); 45 C.F.R. § 431.416.* Forgoing notice and comment unnecessarily is “contrary to the interest of the beneficiaries, as well as of Texas and CMS, because it deprive[s] beneficiaries and other interested stakeholders of the opportunity to comment on and potentially influence the state’s request to extend a complex demonstration.” April 16 Letter at 2. Improper exemption also “deprive[s] Texas and CMS of the benefit of public comments that might have helpfully informed Texas’s design of the extension request and the decision to approve it.” *Id.* The “interests of the beneficiaries and the public generally [are] harmed by the inability to comment on how the requested extension could affect their access to high quality healthcare or to suggest new or alternative approaches for how the state could better achieve the goals of the demonstration.” *Id.* at 5.

Plaintiffs have therefore not carried their heavy burden to demonstrate that the law and facts clearly favor their argument on the merits, and their request for a mandatory preliminary injunction should be denied.

**v. CMS’s April 16 Letter Did Not Constitute Agency Action**

Plaintiffs claim that CMS improperly exercised an authority that it did not possess in its April 16, 2021 letter. However, in reality, although the parties described the April letter as a “rescission” or “withdrawal,” the agency was not in fact exercising any authority via the April letter. The April letter was merely an acknowledgement and notice to Plaintiffs that the action the agency purported to take in the January 15, 2021 letter, approval of the extension request

without a federal notice and comment period, was void ab initio. *See generally* April 16 Letter. Because the purported action in the January 15 Letter was null and void by operation of law, it was not necessary, or possible, for CMS to take any action to further undo the approval. Instead the April 16 Letter is in effect merely a notice to Plaintiffs that the January 15 approval lacked legal effect.

**vi. If the April 16 Letter Constitutes Agency Action, CMS Acted Within Its Authority**

If the Court does not agree that CMS's April 16 Letter is merely an acknowledgment and notice to Plaintiffs that the January 15 Letter is void, Plaintiffs still cannot show a likelihood of success on the merits. “[I]t is generally accepted that in the absence of a specific statutory limitation, an administrative agency has the inherent authority to reconsider its decisions.”

*Macktal v. Chao*, 286 F.3d 822, 825-26 (5th Cir. 2002). Section 1315(a), under which Plaintiffs requested and CMS purportedly approved the demonstration extension, *see infra*, does not contain any such “statutory mandate limiting further review of an agency order.” *Id.* at 826; *see also* 42 U.S.C. § 1315(a). An agency may, using its inherent authority, reconsider any decision not so limited so long as that reconsideration is not “arbitrary, capricious, or an abuse of discretion,” the reconsideration “occurs within a reasonable time after the first decision, and notice of the agency’s intent to reconsider [is] given to the parties.” *Macktal*, 286 F.3d at 826. CMS satisfied these requirements.

A court may not set aside agency action as arbitrary and capricious or an abuse of discretion unless:

the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

*Sierra Club v. United States EPA*, 939 F.3d 649, 663-64 (5th Cir. 2019). This review “is narrow and [the court] must be mindful not to substitute [its] judgment for that of the agency.” *Id.* (citation omitted). “Arbitrary and capricious review asks ‘whether [the] agency articulated a rational connection between the facts found and the decision made.’” *Worldcall Interconnect, Inc. v. FCC*, 907 F.3d 810, 817 (5th Cir. 2018) (quoting *ExxonMobil Pipeline Co. v. U.S. Dep’t of Transp.*, 867 F.3d 564, 571 (5th Cir. 2017)).

In this case, as explained in detail *supra* at 16-19, CMS made a legal decision based on the facts presented by Texas in its application for public notice exemption that the requirements of CMS’s own regulation were not satisfied. *See April 16 Letter*. There is no allegation that CMS considered any impermissible factors. Moreover, Plaintiffs’ allegation that CMS failed to consider reliance interests is both untrue, *see April 16 Letter* at 7, and irrelevant. CMS did consider any reliance interests and determined that none had accrued because THTQIP was operating on materially the same terms as it had been before the January approval and no material programmatic changes had yet been implemented. *Id.* In any event, Plaintiffs’ alleged reliance interests, to the extent they exist, have no bearing on whether CMS’s January 15 approval was in excess of CMS’s legal authority to act. Finally, an “agency decision need only have a rational basis, and it does not have to be a decision which the court would have made.” *Id.* The April 16 Letter articulates a rational connection between those facts contained in Texas’s exemption request and CMS’s determination that they did not satisfy the requirements of the public notice exemption regulations. *See April 16 Letter*. Thus, to the extent CMS took any action in its April 16 Letter, that action was not arbitrary, capricious, or an abuse of discretion.

CMS’s April 16 Letter was also issued within a reasonable time. There is no specific time period that is definitively reasonable under this standard, but the April 16 Letter clearly qualifies.

Only three months elapsed between the January 15 and April 16 letters. And at the time CMS sent its April 16 Letter, there was still over a year and a half remaining before Texas's demonstration project was set to expire. Finally, Plaintiffs received notice of the agency's intent to reconsider its decision because the April 16 Letter, to the extent it represents any agency action, is not final. At the time CMS issued the letter, Plaintiffs had at least two avenues within the administrative process to prevent the April 16 Letter from taking permanent effect, and indeed they have pursued both in addition to this lawsuit. As described *supra* at 13, Plaintiffs filed an administrative appeal with the DAB rendering the April 16 Letter a non-final decision and preventing it from taking effect until the conclusion of the appeal. Plaintiffs also reapplied for an extension of the demonstration project as suggested by the April 16 Letter.

#### **vii. Texas's Additional Merits Arguments Are Unavailing**

Plaintiffs' remaining arguments fail to demonstrate a likelihood of success on the merits because they misunderstand the nature of the April 16 Letter and misread the requirements of the applicable statute and regulations.

First, Plaintiffs conflate the three independent approval authorities granted to CMS with regard to demonstration projects. Based on the circumstances of the extension request and the nature of the intended extension, CMS may consider approval through 42 U.S.C. §§ 1315(a), (e), or (f). *See Cash Decl. ¶ 6; 42 C.F.R. § 431.412(c)* (explaining different conditions applicable to extension requests under the different authorities of sections 1315(a), (e), and (f)); 42 C.F.R. § 431.424(d)(1) (stating that sections 1315(a), (e), and (f) create separate extension authorities). Plaintiffs premise several of their arguments on the requirements of § 1315(f), but their extension request sought approval under § 1315(a). Cash Decl. ¶ 12. Moreover, neither the initial extension requested nor the modified extension purportedly approved by the January 15 Letter

were permissible under § 1315(e) or (f) authority and thus must necessarily have been considered under § 1315(a). *See Cash Decl.* ¶¶ 7-9, 11-12. The most obvious indicator that the extension at issue cannot be subject to the requirements of § 1315(f) is the length of the extension. Section 1315(f) mandates that extensions approved under its authority be no longer than three years. Cash Decl. ¶ 8; 42 U.S.C. § 1315(f)(6) (“An approval of an application for an extension of a waiver project under this subsection *shall* be for a period not to exceed 3 years.”) (emphasis added).<sup>5</sup> If the requirements of § 1315(f) were implicated by the extension at issue, which according to the January 15 Letter is for a period of nearly ten years, the approval would have been in excess of statutory authority (and void) for this additional reason as well. Accordingly, none of Plaintiffs’ arguments premised on the alleged requirements of § 1315(f), including the 120-day limit to respond to applications and the automatic approval of extension applications, are legally correct and they have no likelihood of success on the merits.

Plaintiffs also misinterpret § 1315(a) to impose a restriction on CMS’s authority to disapprove demonstration projects or extensions that does not exist. Plaintiffs allege that CMS “may only approve or disapprove an extension of a demonstration project to the extent that choice ‘is likely to assist in promoting the objectives’ of Medicaid.” PI Mot. at 18. However, § 1315(a) does not impose any restrictions whatsoever on CMS’s authority to deny or simply not respond to an application. If CMS chooses to waive any of the requirements of Medicaid, it may only do so to the extent that “in the judgment of the Secretary, [the project] is likely to assist in promoting the objectives” of Medicaid. 42 U.S.C. § 1315(a). But, if CMS instead decides not to waive any requirements, that decision is entirely discretionary; it does not require any finding by

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<sup>5</sup> Section 1315(f)(6) contains an exception that permits extensions of 5 years in the sole case of “a waiver described in section 1396n(h)(2) of this title,” a specific waiver not at issue here. Cash Decl. ¶ 7 n.1.

the Secretary that the requested waiver is not likely to assist in promoting the objectives of Medicaid. *Cf. id.* (“the Secretary *may* waive compliance” (emphasis added)).

For the same reason, the April 16 Letter does not violate any of CMS’s regulations. As Plaintiffs note, CMS does not assert any regulatory authority to rescind the January approval in its letter. PI Mot. at 20. That is because the April 16 Letter does not reflect any agency action taken by CMS. Even if the letter were agency action, it would be action taken under the inherent authority of CMS to reconsider its own decisions, *see supra* at 21-23. Plaintiffs are simply wrong that the existence of other specific regulatory authorities compels a finding that this inherent authority does not exist. *Cf. Macktal v. Chao*, 286 F.3d at 825-26 (5th Cir. 2002) (“[I]t is generally accepted that in the absence of a specific statutory limitation, an administrative agency has the inherent authority to reconsider its decisions.”).

Plaintiffs contend that the April 16 Letter does not satisfy the conditions for either termination of a demonstration project or withdrawal of a waiver under 42 C.F.R. § 431.420. PI Mot. at 21. First, as described *supra*, the April 16 Letter merely provides notice to Plaintiffs of the operation of law and does not reflect any action by CMS. Second, even if that were not the case, the voiding of the January 15 approval neither terminated the demonstration project nor withdrew any waivers that were part of the existing demonstration project. Although CMS is currently treating the January approval as effective as required by the DAB regulations, the original demonstration project has not been terminated and will remain ongoing with all waivers through September 30, 2022 if the administrative appeal ends or is disposed in CMS’s favor. Therefore, these regulations are clearly inapplicable. Third, because CMS did not take any action through the April 16 Letter, its inaction cannot be arbitrary and capricious for failing to comply with the requirements of various regulations that were not implicated, Plaintiffs state that the

April 16 Letter is fatally defective for failing to comply with various regulations, PI Mot. at 23, but this allegation is entirely irrelevant. The January 15 approval would be in excess of agency authority and void as a matter of law whether or not the April 16 Letter ever existed, and Plaintiffs would be in the same position. Similarly, if the April 16 Letter is a reconsideration under CMS's inherent authority, it need only comply with the conditions explained *supra* at 21-22.

Each of Plaintiffs' arguments that the April 16 Letter violates the APA are also meritless for the same reasons.<sup>6</sup> The April 16 Letter does not represent any agency action and is merely a notice to Plaintiffs that the January 15 approval was void by operation of law. Issuing the April 16 Letter did not create any obligation to provide a notice and comment period, to consider Texas's alleged reliance interests, or to consider alternative remedies. Because CMS acted in excess of its authority in granting the approval contained in the January 15 Letter, it neither had nor exercised any authority to alter the January approval in its April 16 Letter. The April 16 Letter was merely a description of the legal state of affairs surrounding Plaintiffs' extension request, and as such it was not an agency action that created any rights or duties under the APA.

If, in the alternative, the April 16 Letter constituted agency action under CMS's inherent authority to reconsider, that action also was not arbitrary and capricious for the reasons explained *supra* at 22-23. While the agency's exercise of inherent authority to reconsider creates an

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<sup>6</sup> Plaintiffs' reliance on COVID-related statutes that do not actually govern the dispute in this case is also misplaced. PI Mot. at 19-20. They do not contend that any of the statutes cited actually speak "specifically to the topic at hand." *FDA v. Brown & Williamson*, 529 U.S. 120, 133 (2000). Nor do they contend that the statutes in any way amended CMS's statutory obligation to provide a public notice and comment process before approving the extension of a demonstration project. Moreover, even if these statutes were relevant (and they are not) Texas's requested demonstration extension does not address the COVID-19 pandemic and the April 16 Letter does not create an imminent risk to the provision of health services. *See supra* at 16-19.

obligation to notify the regulated entity of the reconsideration, unlike the specific regulatory authorities, there is no requirement to provide a period of public notice and comment or to consider alternative remedies. *See supra* at 21-22. To the extent Plaintiffs argue that reliance interests are an “important aspect of the problem” that must be considered under the arbitrary and capricious standard, that argument also fails as discussed *supra* at 22.

Finally, for the reasons enumerated *supra* at 16-19, Plaintiffs’ claim that the April 16 Letter is arbitrary and capricious because its underlying legal premise is not in accordance with law fails. CMS “materially erred” in granting Plaintiffs’ unsupported request for exemption from notice and comment and Plaintiffs have no likelihood of success on the merits of that claim.

**b. Plaintiffs Have Not Demonstrated That The Balance Of The Equities Or The Public Interest Favors An Injunction**

“Federal courts have considered the balance of equities and public interest factors together as they overlap considerably.” *Texas v. United States*, Case No. 21-cv-00003, \_\_ F. Supp. 3d \_\_, 2021 U.S. Dist. LEXIS 33890, at \*136 (S.D. Tex. Feb 23, 2021); *see also Nken v. Holder*, 556 U.S. 418, 435 (2009) (“These factors merge when the Government is the opposing party.”). “In weighing equities, a court ‘must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.’” *Texas*, 2021 U.S. Dist. LEXIS 33890, at \*136 (quoting *Winter v. NRDC, Inc.*, 555 U.S. 7, 24 (2008)). Meanwhile, “the public interest factor requires the court to consider what public interests might be injured and what public interests might be served by granting or denying a preliminary injunction.” *Id.*

Because of the pendency of the DAB appeal and the requirement that CMS take no action on the April 16 Letter, both of these prongs of the analysis favor denial of the preliminary injunction. As explained *supra* at 8, in light of the pending administrative appeal, Plaintiffs have

failed to allege any harm at all, much less irreparable harm. If the requested preliminary injunction were granted, it would have no effect at all on the interests of Plaintiffs because it would be entirely duplicative of relief Plaintiffs are already receiving as a result of their administrative appeal.<sup>7</sup> Because the requested preliminary injunction would provide no additional relief, neither the balance of the equities nor the public interest favor its imposition.

The burden is on Plaintiffs to establish that all four factors “clearly favor” granting the requested injunction. Because Plaintiffs have failed to demonstrate that either the balance of equities or the public interest favor their position, the injunction must be denied.

#### **V. Plaintiffs’ Suit Should Be Dismissed For Lack Of Subject Matter Jurisdiction**

As explained *supra* at 13-15, the Court lacks jurisdiction to consider Plaintiffs’ claims because Plaintiffs are engaged in an ongoing administrative appeal. The APA waiver of sovereign immunity has not been activated in this case because there is no final agency action. Moreover, Plaintiffs do not have standing to bring this suit and their claims are not ripe while the DAB appeal is pending.

Although Defendants maintain that this Court is without jurisdiction to consider Plaintiffs’ claims, if the Court does not agree, it should nevertheless stay district court proceedings pending resolution of the administrative appeal to further the interests of judicial economy. Because the DAB is considering the same “action” Plaintiffs challenge here, and because Plaintiffs will continue to receive the same relief requested in their motion for

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<sup>7</sup> Similarly, because the operation of the DAB regulations imposes the same conditions as those requested for the preliminary injunction, a preliminary injunction would have no additional effect on the interests of the Defendants during the pendency of the DAB appeal. However, entry of a preliminary injunction would otherwise injure Defendants and the public interest because it would both require CMS to act in excess of its statutory authority, and would require CMS to expend resources in execution of the January 15 approval that it may later need to recoup.

preliminary injunction during the pendency of that appeal, a stay of the Court's procedures will best serve the interests of all parties.

**VI. Conclusion**

For the reasons explained herein, the Court should decline to exercise jurisdiction over this matter. Whether or not the Court exercises jurisdiction over this matter it should deny Plaintiffs' Motion for Preliminary Injunction.

Dated: July 26, 2021

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing document was served on all counsel of record by operation of the court's electronic filing system and can be accessed through that system.

DATED: July 26, 2021

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